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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, Defendant.	No. 2:21-CV-00326-TOR DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT 11/22/22 at 2:30 p.m. With Oral Argument

I. INTRODUCTION

This is a case that never should have been filed. The Medicare claims at issue were paid *four months* before Plaintiff filed his complaint. The claims were paid in accordance with a judgment Plaintiff obtained in a prior case, *Olsen I*. The payment of these claims means that Plaintiff received the Medicare coverage to which he was entitled—and that, as a result, there is no Article III case or controversy for this Court to resolve. The case should be dismissed for lack of jurisdiction.

Separately, the administrative ruling Plaintiff is challenging, CMS 1682-R (Jan. 12, 2017), has been formally rescinded and replaced by the Secretary through notice-and-comment rulemaking and a recent administrative ruling, CMS 1738-R (May 13, 2022). The Secretary's new policy provides coverage for virtually all continuous glucose monitor ("CGM") devices, including "non-therapeutic" devices for which coverage was formerly excluded under CMS 1682-R. As the Tenth Circuit recently recognized in a companion case with nearly identical claims, this new policy renders any challenge to CMS 1682-R moot. *Smith v. Becerra*, 44 F.4th 1238 (10th Cir. 2022). The fact that Plaintiff's challenge to CMS 1682-R is moot independently warrants dismissal for lack of jurisdiction.

II. FACTS

There are two Medicare reimbursement claims at issue in this case: (1) a claim for CGM sensors with a date of service of April 19 – July 18, 2019 (the "April 2019 claim"), and (2) a claim for CGM sensors with a date of service of March 10, 2021 (the "March 2021 claim"). As outlined below, both claims were paid by Medicare on July 15, 2021. The claims were paid in recognition of a judgment Plaintiff obtained against the Secretary in a prior case, *Olsen v. Becerra*, Case No. 20-CV-00374-SMJ (E.D. Wash.) ("*Olsen I*"), which held that Plaintiff's CGM device met the definition of "durable medical equipment" for which Medicare is required to provide coverage.

Three months *after* the Secretary paid the claims, an Administrative Law Judge ("ALJ") and the Medicare Appeals Council issued decisions that purport to deny

coverage. The ALJ and the Medicare Appeals Council were not aware of the *Olsen I* judgment, or the fact that the claims had already been paid, when they issued their decisions. To the extent these decisions amount to "denials" of the claims, they exist on paper only, and have not impacted Plaintiff in any way.

A. *Olsen I* Proceedings (2019-2021)

Plaintiff filed the *Olsen I* case in 2019. His claims in that case challenged Medicare's denial of coverage for the specific type of CGM device Plaintiff uses. This Court (Judge Mendoza) entered summary judgment for Plaintiff, holding that Plaintiff's CGM device meets the definition of "durable medical equipment" under the Medicare regulations, and must therefore be covered. *Olsen I*, ECF No. 39. The summary judgment order was entered on February 23, 2021. *Id.* Thereafter, on April 20, 2021, the Court awarded Plaintiff attorney's fees and costs under the Equal Access to Justice Act. *Id.* at ECF No. 50. The order awarding fees and costs contained a finding that the government's litigation position was "so obviously wrong as to be frivolous." *Id.*

B. Payment of April 2019 and March 2021 Claims (July 2021)

The April 2019 and March 2021 claims were paid by Medicare on **July 15, 2021**. AR 566.[1] Payment was issued by the Secretary's Medicare Administrative Contractor, Noridian Healthcare Solutions ("Noridian"), to the company that supplied

[1] "AR" refers to the Administrative Record filed at ECF No. 32.

Plaintiff with the CGM sensors, MiniMed Distribution Corp. ("MiniMed"). AR 532, 539-40. The Secretary paid these claims in accordance with the *Olsen I* judgment, which the Secretary viewed as having an issue preclusive effect on all of Plaintiff's then-pending and future CGM claims. AR 510-31; ECF No. 42-1 at ¶¶ 6-7, 9. The April 2019 and March 2021 claims were paid at the same time as nine other CGM claims Plaintiff had submitted to Medicare before the *Olsen I* judgment. AR 539-40, 566-69; ECF No. 41 at ¶ 76.

C. Post-Payment Administrative Claim "Denials" (October 2021)

Three months *after* the Secretary paid the claims, the ALJ and the Medicare Appeals Council issued administrative decisions that purport to deny coverage for the claims. Those decisions were issued on October 22, 2021 (as to the April 2019 claim) (AR 3-12), and October 26, 2021 (as to the March 2021 claim) (AR 385-90). Both decisions purport to deny coverage under an administrative ruling (which has since been replaced and rescinded) known as CMS 1682-R.

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The timing of these decisions is crucial. Below is a chronological summary:

April 2019 Claim	**Date**
Initial Denial by Noridian (MAC)	6/14/2019
Redetermination Request (MAC)	7/5/2019
Redetermination Decision (MAC)	7/25/2019
Reconsideration Request (QIC)	10/7/2019
Reconsideration Decision (QIC)	11/26/2019
ALJ Hearing Request	12/3/2019
ALJ Hearing	1/8/2020
ALJ Decision	1/31/2020
Appeal to Medicare Appeals Council	2/11/2020
Olsen I Judgment	2/23/2021
Olsen I Attorney's Fees Ruling	4/20/2021
CLAIM PAID	7/15/2021
Medicare Appeals Council Decision (Challenged Decision)	**10/22/2021**

March 2021 Claim	**Date**
Olsen I Judgment	2/23/2021
Initial Denial by Noridian (MAC)	4/16/2021
Olsen I Attorney's Fees Ruling	4/20/2021
Redetermination Request (MAC)	5/3/2021
Redetermination Decision (MAC)	6/16/2021
Reconsideration Request (QIC)	6/30/2021
CLAIM PAID	7/15/2021
Reconsideration Decision (QIC)	8/24/2021
ALJ Hearing Request	9/7/2021
ALJ Hearing	10/8/2021
ALJ Decision (Challenged Decision)	**10/26/2021**

The fact that the ALJ and the Medicare Appeals Council "denied" the claims three months after the Secretary paid them in accordance with the *Olsen I* judgment is admittedly odd. But the explanation is simple: neither tribunal was aware of the *Olsen I* judgment, or the fact that the claims had already been paid in accordance with that judgment. ECF No. 42-1 at ¶ 11.

Both parties are partly to blame for this unusual circumstance. The Secretary took the necessary steps to ensure that its claims processing contractor, Noridian, paid the claims in accordance with the *Olsen I* judgment. AR 510-31. The Secretary did not, however, communicate with the various entities that handle administrative appeals. ECF No. 42-1 at ¶ 11. The end result was that Noridian paid the claims, but the ALJ and the Medicare Appeals Council were not informed.

Plaintiff, for his part, did not advise the ALJ or the Medicare Appeals Council of the *Olsen I* judgment, or the fact that the Secretary had paid the claims. Plaintiff had a tailor-made opportunity to do so during a hearing before the ALJ on October 8, 2021, but he remained silent. AR 391-98. Rather than transparently requesting that coverage be granted pursuant to the *Olsen I* judgment (or disclosing that the claims had already been paid), Plaintiff took the opposite approach, *insisting that the ALJ deny coverage* under CMS 1682-R. AR 395-98.

In any case, the ALJ and Medicare Appeals Council decisions have no practical or legal effect. To the extent they can be construed as "denials" of the subject claims, the denials exist on paper only. They did not prevent Plaintiff from receiving the

Medicare coverage to which he was entitled, or impact him in any other way, because the claims had been paid three months earlier.

D. The Secretary's Policy Changes Regarding CGM Coverage (2020-2022)

Plaintiff challenges the administrative "denials" of the April 2019 and March 2021 claims at least in part on the grounds that the denials were based on CMS 1682-R, which Plaintiff contends was issued illegally. CMS 1682-R distinguished between "therapeutic" (or "non-adjunctive") CGM devices that were approved by the United States Food and Drug Administration ("FDA") to be relied upon in making treatment decisions for managing diabetes, and "non-therapeutic" (or "adjunctive") CGM devices, which had not received FDA approval. CMS 1682-R held that Medicare would cover the former category of CGMs, but not the latter.[2]

The Secretary, through the Centers for Medicare & Medicaid Services ("CMS") has now rescinded and replaced CMS 1682-R, and extended Medicare coverage to all CGM devices, both therapeutic and non-therapeutic, with an exception not relevant here for devices that use a smartphone as the sole receiver. CMS accomplished this goal in stages. On November 4, 2020, CMS published a proposed rule, proposing to replace CMS 1682-R with a new rule that would generally classify CGM devices as durable medical equipment under Medicare Part B, regardless of whether the device was classified as therapeutic ("non-adjunctive") or non-therapeutic ("adjunctive"). 85

[2] At the time CMS 1682-R was issued in 2017, there was only one non-adjunctive CGM device that had been approved by the FDA: the Dexcom G5 CGM.

Fed. Reg. 70,358, 70,398–70,404 (Nov. 4, 2020). After receiving and considering public comment on the proposed rule, CMS issued its final rule on December 28, 2021. 86 Fed. Reg. 73,860, 73,896–73,902 (Dec. 28, 2021) (the "DME Final Rule"),[3] available here. The DME Final Rule replaced CMS 1682-R and expanded the classification of durable medical equipment to both therapeutic and non-therapeutic CGMs. *Id.* at 73,902. Under the DME Final Rule, all CGM devices (except those that use a smartphone as the sole receiver)[4] are considered to be "primarily and customarily used to serve a medical purpose" and "durable medical equipment" as those terms are defined in the Medicare coverage regulations. *See id.* at 73,899. The DME Final Rule also clarified that CMS 1682-R "only addressed whether CGMs meet the Medicare definition of [durable medical equipment] and did not address whether insulin pumps that can also perform the function of a CGM are [durable medical equipment] since insulin pumps are already classified as [durable medical equipment]." *Id.* at 73,898. The agency recognized, however, that claims for continuous glucose-monitor sensors and transmitters used with insulin pumps "are being denied inappropriately based on CMS-1682-R." *Id.* The DME Final Rule became effective February 28, 2022. *See id.* at 73,860.

CMS took additional steps to make this policy change apply to earlier dates of

[3] The acronym DME refers to durable medical equipment. *See* 42 U.S.C. § 1395x(n).

[4] A smartphone does not fit the definition of durable medical equipment. *See* 42 C.F.R. § 414.202. That limited exception does not apply to the claims at issue here.

service (*i.e.*, those prior to the February 28, 2022, effective date of the DME Final Rule). On February 25, 2022, CMS issued a technical direction letter, TDL-220257, to its Durable Medical Equipment Medicare Administrative Contractors ("DME MACs"), instructing them to apply the policy of the DME Final Rule to reimbursement claims with dates of service that predate the February 28, 2022 effective date of the rule. *See* ECF No. 20-1 (TDL-220257 (Feb. 25, 2022)). TDL-220257 states:

> The [DME Final Rule] replaced a 2017 CMS Ruling, CMS-1682-R ("2017 Ruling"), regarding CGMs. Pursuant to this [technical direction letter], the DME MACs shall apply the coverage and payment provisions of the [DME Final Rule] to valid reimbursement claims and appeals for CGM monitors or receivers and/or necessary supplies and accessories supplied prior to February 28, 2022. The [DME Final Rule] obviates the need for further application of the 2017 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or nonadjunctive CGMs, non-therapeutic or adjunctive CGMs can also meet the Medicare definition of durable medical equipment (DME) at 42 C.F.R. § 414.402.

Id. at 1-2.

Finally, on May 13, 2022, the agency issued a new CMS Ruling that formally rescinds CMS 1682-R. That new ruling, CMS 1783-R, instructs contractors and Department of Health and Human Services employees at all levels of the Medicare claims-review process—including administrative law judges and the Medicare Appeals Council—to apply the terms of the DME Final Rule to valid pending or future claims and appeals, regardless of the date of service. ECF No. 44-1 (CMS 1738-R (May 13, 2022)). CMS 1783-R explains that, "[t]aken together, the [DME

Final Rule] and this Ruling prohibit further application of [CMS 1682-R] on CGMs," *id.* at 6, and require application of CMS's determination that "the following types of CGMs shall be classified as [durable medical equipment]: therapeutic or non-adjunctive CGMs; non-therapeutic or adjunctive CGMs; and insulin pumps that also function as a CGM or receiver," *id.* at 11.

Both TDL-220257 and CMS 1738-R apply to Medicare reimbursement claims that have been "valid[ly] appeal[ed]." TDL-220257 at 2-3; CMS 1738-R at 9-10.

III. ARGUMENT

Subject matter jurisdiction is lacking for two independent reasons. First, the Secretary paid the April 2019 and March 2021 claims four months before the case was filed. For that reason, there is no "case or controversy" on which Article III jurisdiction can be predicated. Second, the Secretary has formally rescinded and replaced CMS 1682-R. That development moots Plaintiff's challenges to CMS 1682-R and eliminates any jurisdiction that may have originally existed.

Because jurisdiction is lacking, the Court lacks authority to take any action other than to dismiss the case without prejudice. However, if the Court concludes it does have jurisdiction, the appropriate course is to remand the case with instructions to vacate the administrative decisions that purport to deny coverage pursuant to the now-rescinded CMS 1682-R, which relief the Secretary has consented to from the very beginning.

A. The case should be dismissed for lack of Article III jurisdiction because the Medicare claims at issue were paid months before the case was filed.

"Article III of the Constitution confines the judicial power of federal courts to deciding actual 'Cases' or 'Controversies.'" *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013) (citing U.S. Const. Art. III § 2). "No principle is more fundamental to the judiciary's proper role in our system of government[.]" *Raines v. Byrd*, 521 U.S. 811, 818 (1997). The presence of a disagreement, "however sharp and acrimonious it may be," does not by itself satisfy the case or controversy requirement. *Hollingsworth*, 570 U.S. at 704 (quotation omitted). "The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." *Id.*

It is undisputed that the Medicare claims at issue were paid more than four months before this case was filed. It is further undisputed that the administrative decisions from which Plaintiff appeals, which purport to deny coverage for the claims, did not have the effect of denying coverage. In short, it is undisputed that Plaintiff received the Medicare coverage to which he was entitled.

As a matter of law and simple common sense, these facts do not present a live case or controversy. There is no need for an order "direct[ing] the Secretary to *make appropriate payment for the claims*" as Plaintiff repeatedly prays for in his complaint.

ECF No. 1 at ¶¶ 92, 93, 95, 96, 98, 99, 101, 102, 104, 105 (emphasis added). The Secretary *has* made "appropriate payment" for the claims—and did so months before the case was filed. It is difficult to imagine a more textbook illustration of a case that does not meet this basic Article III jurisdictional requirement.

Plaintiff may argue that a live controversy exists because the Secretary could seek "recoupment" of the payments in the future. That argument fails for two reasons. First, the argument is purely speculative. A mere possibility that the Secretary might seek recoupment at some unspecified time does not suffice. Plaintiff must show that recoupment of the payments is "actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Plaintiff cannot do so because the Secretary has no intention of clawing back the payments, which would contravene both the *Olsen I* judgment and the Secretary's current policies.[5]

Second, the only grounds on which the Secretary could theoretically pursue recoupment is that the claims were paid in contravention of the ALJ and Medicare Appeals Council decisions that purport to deny coverage. But those decisions rely on CMS 1682-R, which the Secretary has since formally rescinded and replaced through

[5] Any suggestion that the Secretary admitted in its answer that he might pursue recoupment (*see, e.g.*, ECF No. 22 at 6-7), is incorrect. No such admission was made. The complaint alleges that the Secretary can "recoup overpayments" pursuant to 42 C.F.R. § 405.352 "if he determines that he has overpaid a claim." ECF No. 1 at ¶ 78. That is an accurate statement of the law, which the Secretary admitted. The complaint does not allege that the Secretary has taken any steps toward pursuing recoupment of the payments at issue, or that he has plans to do so in the future. The Secretary has not taken any such steps, and has no plans to do so in the future.

notice and comment rulemaking and CMS 1738-R. Thus, even if the Secretary was inclined to pursue recoupment, which he is not, he would lack any legal justification for doing so. In short, recoupment is a red herring.

In apparent recognition that his *own* claims do not present a live controversy, Plaintiff has recently resorted to asserting claims on behalf of other similarly-situated Medicare beneficiaries. *See, e.g.*, ECF No. 51 at 1-2 (arguing, without empirical support, that the Secretary is "responsible for the deaths of thousands of Americans" and that an injunction should issue to "bar[] the Secretary from repeating the conduct that killed so many"); ECF No. 64 at 11 (urging appointment of a special master to oversee all CGM claims submitted to Medicare by Type I diabetics). This tactic is unavailing. To establish Article III jurisdiction, Plaintiff must demonstrate an injury that is *personal to him*:

> The Art. III judicial power exists only to redress or otherwise to protect against injury *to the complaining party*, even though the court's judgment may benefit others collaterally. A federal court's jurisdiction therefore can be invoked *only when the plaintiff himself* has suffered some threatened or actual injury resulting from the putatively illegal action.

Warth v. Seldin, 422 U.S. 490, 498 (1975) (emphasis added) (quotation and citation omitted).

At bottom, this case should never have been filed. Plaintiff received the Medicare coverage to which he was entitled. Due to a miscommunication on the Secretary's part, and what appears to have been calculated concealment on Plaintiff's part, the ALJ and the Medicare Appeals Council issued after-the-fact decisions that

purport to deny coverage. But those "denials" exist on paper only. They did not impact Plaintiff in any way. The Court should reject Plaintiff's bid to manufacture Article III jurisdiction out of those meaningless pieces of paper.[6]

B. Plaintiff's challenges to CMS 1682-R and his requests for injunctive relief and appointment of a special master are moot because CMS 1682-R has been formally rescinded and replaced.

For the reasons explained above, jurisdiction is lacking because the subject claims were paid before the case was filed. But jurisdiction is also lacking for an independent reason: the administrative ruling that Plaintiff is challenging, CMS 1682-R, has been formally rescinded and replaced through notice and comment rulemaking and CMS 1738-R. Those developments moot Plaintiff's challenges to CMS 1682-R and his request for permanent injunctive relief and appointment of a special master.

The Tenth Circuit's recent decision in *Smith v. Becerra*, 44 F.4th 1238 (10th Cir. 2022), is directly on point. The plaintiff in *Smith*, who was represented by the same lead counsel who represents Plaintiff in this case, asserted claims to invalidate

[6] While not relevant for jurisdictional purposes, Defendant questions Plaintiff's motivation for filing the case. Plaintiff filed the case and immediately demanded that the Secretary stipulate to the entry of a nationwide injunction barring enforcement of CMS 1682-R. When the Secretary refused that demand, Plaintiff moved for a nationwide preliminary injunction. ECF No. 6. Plaintiff's briefing was replete with claims that the Secretary "denied" his claims "in bad faith." *See, e.g.*, ECF No. 6 at 1, 4, 10; ECF No. 22 at 1-2. Plaintiff was not transparent about the fact that the claims had been paid, either in his complaint or his preliminary injunction briefing. *See* ECF No. 34 (order directing Plaintiff to provide a full accounting of any claims that had not been paid). It seems reasonable to infer from these early developments that Plaintiff and his counsel hoped to score a quick victory before the true facts became known.

CMS 1682-R and to declare that her CGM device was covered by Medicare. *Smith*, 44 F.4th at 1241-42, 1245-46, 1249. The Secretary argued that the claims were moot due to (1) the adoption of the DME Final Rule; (2) the issuance of TDL 220257; and (3) the formal rescission of CMS 1682-R through the issuance of CMS 1738-R. *Id.* at 1248. The Court agreed:

> We dismiss the appeal as moot. The Final Rule concerning future claims for CGMs, coupled with the recent issuance of Technical Direction Letter 220257 and CMS-1738-R, fully redress Smith's equitable claims. Vacating CMS-1682-R and declaring that CGMs are durable medical equipment covered by Medicare would have no effect because CMS has already rescinded CMS-1682-R and issued a formal rule classifying CGMs and their supplies as durable medical equipment. In short, Smith no longer suffers from an actual or imminent injury that can be redressed by this court.

Id. at 1246.

While not binding on this Court, *Smith* is highly persuasive authority. As the Tenth Circuit correctly concluded, the DME Final Rule, TDL 220257, and the formal rescission of CMS 1682-R, taken together, "ensure that pending and future claims for CGMs . . . will be covered by Medicare." *Id.* at 1242. Collectively, "these changes mean that the Secretary no longer has any basis upon which to deny . . . pending or future claims." *Id.* at 1248. Any challenge to the legality of CMS 1682-R, and any request for declaratory or injunctive relief addressed to CMS 1682-R specifically or to coverage for CGMs in general, is therefore moot. *Id.* at 1242, 1246-47, 1248-50.

Smith also addresses the "voluntary cessation" exception to mootness, which the Secretary anticipates Plaintiff will invoke in his response. The voluntary cessation

exception provides that a case is not moot when the defendant has stopped engaging in the challenged conduct, but remains free to resume it again in the future. *Fikre v. Fed. Bureau of Investigation*, 904 F.3d 1033, 1037 (9th Cir. 2018). To obtain a dismissal on mootness grounds, the defendant must show that "the challenged conduct cannot reasonably be expected to start up again." *Id.* The *Smith* Court emphatically rejected the plaintiff's reliance on the voluntary cessation exception, holding that there was no reasonable possibility that the Secretary would continue to deny CGM claims under CMS 1682-R:

> [T]here is a minimal risk that the Secretary will suddenly revert to his rescinded policy of denying CGM claims given the wholesale change in policy that has developed over the past several years. To undo his policy recognizing CGMs as durable medical equipment, the Secretary would need to take the unlikely steps of disavowing his previous support for the coverage of CGMs, replacing the Final Rule—which can only be done after a notice and comment period, rescinding the Technical Direction Letter, and withdrawing CMS-1738-R.
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> * * *
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> It cannot "reasonably be expected" that CMS would suddenly revert to denying CGM claims when it has gone through the lengthy rulemaking process and concluded in the Final Rule, Technical Direction Letter, and CMS-1738-R that CGMs are durable medical equipment covered by Medicare. Unraveling those regulatory changes seems improbable, especially given that CMS has determined it to be more cost effective to pay pending CGM claims rather than continue litigating them.

Id. at 1251, 1252.

The legal claims in *Smith* are virtually identical to the claims Plaintiff is pursuing here. From a factual standpoint, the cases are substantially similar. The

main distinction between this case and *Smith* is that the Medicare claims at issue here were paid *before* the challenged administrative decisions were issued, and *before* the case was filed. That distinction makes the Tenth Circuit's reasoning even more persuasive on the facts presented here, especially on the question of voluntary cessation.

The Court should adopt *Smith's* persuasive reasoning and dismiss the case as moot in light of the Secretary's adoption of the DME Final Rule, the issuance of TDL 220257, and the formal rescission of CMS 1682-R, all of which ensure that Plaintiff's pending and future CGM claims will be covered by Medicare.

C. Plaintiff's due process claim fails as a matter of undisputed fact and well-established law.

Plaintiff's sixth cause of action is a constitutional due process claim under the Fifth and Fourteenth Amendments. ECF No. 1 at ¶¶ 106-12. The crux of this claim is that Plaintiff "has a Constitutionally protected property interest in funds due as a result of qualifying claims submitted to Medicare," and that Plaintiff was "deprived [of] his property interest . . . without due process because the Secretary has not appointed a neutral decision maker to consider [his] claims." *Id.* at ¶¶ 108-09.

This claim fails for a host of reasons. From a factual standpoint, there has been no deprivation of a "property interest in funds due" because Medicare *paid* the subject claims. Plaintiff's allegation that he was "deprived" of that interest by the challenged

decisions borders on a Rule 11 violation.[7]

Moreover, assuming *arguendo* that a deprivation of a property interest actually did occur, Plaintiff has not proven that it was *his* property interest that was infringed. Plaintiff has suggested in prior filings that his supplier, MiniMed, covered the full cost of the CGM sensors that are the subject of the April 2019 and March 2021 claims. *See, e.g.*, ECF No. 22 at 10 ("That [Plaintiff] has a CGM at this time is totally dependent on the *generosity of his supplier* and willingness (to date) to provide a CGM *without payment*.") (emphasis added). Documents produced by MiniMed in response to the Secretary's subpoena (*see* ECF Nos. 58, 62), appear to confirm that MiniMed did not charge Plaintiff for any portion of the cost of the sensors. Drake Decl. ¶¶ 4-6, & Ex. A. The fact that Plaintiff did not pay anything for the sensors means that he does not have a constitutionally protected right to reimbursement by Medicare. Any right to reimbursement belongs to MiniMed, not Plaintiff. Accordingly, there are no facts to support a finding that Plaintiff was deprived of a "property interest in funds due."

From a legal standpoint, Plaintiff's due process claim is not cognizable. The essence of procedural due process is notice and an opportunity to be heard. *Mathews*

[7] If the Court were to "direct the Secretary to make appropriate payment for the claims," as Plaintiff requests in his complaint, *see, e.g.*, ECF No. 1 at ¶ 102, the Secretary would be paying the claims twice. It is not at all clear how that request comports with counsel's duty to ensure Plaintiff's claims are factually supported, warranted by existing law, and not presented for an improper purpose. Fed. R. Civ. P. 11(b).

v. Eldridge, 424 U.S. 319, 333 (1976). Plaintiff was afforded both. Plaintiff does not like the decisions reached by the ALJ and the Medicare Appeals Council, but he does not deny that he was afforded an opportunity to participate in the process.

Plaintiff's allegation that the ALJ and Medicare Appeals Council were not "neutral decision makers" does not save the claim. While a neutral decision maker is an important component of procedural due process, "neutrality" in this context refers to the absence of *bias*. *See Clements v. Airport Auth. of Washoe Cnty.*, 69 F.3d 321, 333 (9th Cir. 1995) ("A biased proceeding is not a procedurally adequate one. At a minimum, Due Process requires a hearing before an impartial tribunal.") (citing *Ward v. Village of Monroeville*, 409 U.S. 57, 59-60 (1972). Plaintiff has not alleged, much less proven, that the ALJ and/or the Medicare Appeals Council were biased against him. To the contrary, the thrust of this claim is that the ALJ and Medicare Appeals Council were not "neutral" because they *had no choice but to apply CMS 1682-R* to him and every other CGM claimant. *See* ECF No. 64 at 9 (colorfully arguing that ALJs are "partisans beholden to their master" and (in reference to CMS 1682-R) must follow "whatever ridiculous, illegal, thing [the Secretary] might happen to say").

CMS Rulings are precedential. They are "binding on all CMS components, [and] all HHS components that adjudicate matters under the jurisdiction of CMS," including ALJs and the Medicare Appeals Council. 42 C.F.R. § 401.108(c). The fact that the ALJ and Medicare Appeals Council applied CMS 1682-R in the challenged decisions is not indicative of bias or partiality. It simply means they were doing their

jobs. Plaintiff's frustration that the ALJ and Medicare Appeals Council were not free to disregard CMS 1682-R while that ruling was in effect does not amount to a due process violation. This claim should be dismissed.

D. The Court should dismiss the case without prejudice for lack of Article III jurisdiction, or, alternatively, enter judgment in Plaintiff's favor on Count II with instructions to vacate the challenged administrative decisions.

For the reasons explained in Section III.A, *supra*, jurisdiction has been lacking from the outset because the Secretary paid the subject claims four months before the case was filed. As a result, the Court lacks authority to take any action other than to dismiss the case without prejudice. Fed. R. Civ. P. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, it must dismiss the action."); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.") (citation omitted); *Barke v. Banks*, 25 F.4th 714, 721 (9th Cir. 2022) (dismissal for lack of Article III jurisdiction must be without prejudice).

As discussed in Section III.B, *supra*, the Secretary's rescission and replacement of CMS 1682-R moots Plaintiff's challenge to that administrative ruling and his attendant requests for injunctive and declaratory relief. If the Court disagrees with the Secretary's mootness analysis and concludes that it has Article III jurisdiction over plaintiff's claims, which for the reasons explained it should not,, the appropriate

course would be remand the case to the Secretary with instructions to vacate the ALJ and Medicare Appeals Council decisions that purport to deny coverage pursuant to CMS 1682-R, as the Secretary asked the Court to do from the very beginning, but which Plaintiff repeatedly opposed. *See* ECF Nos. 4, 16, 41 (original answer, amended answer, and second amended answer, all consenting to administrative remand to vacate the challenged agency decisions). The Court could do so by (1) entering judgment in Plaintiff's favor on Count II of the Complaint (violation of 5 U.S.C. § 706(2)(A) for agency action "not in accordance with law") because the ALJ and Medicare Appeals Council decisions from which the plaintiffs appealed to district court are not in accordance with law in light of the Secretary's new policy;[8] and (2) entering judgment in the Secretary's favor on all other claims.

IV. CONCLUSION

The Secretary respectfully requests that the Court dismiss the case without prejudice for lack of jurisdiction. Alternatively, to the extent jurisdiction has been established, the Secretary requests that the Court enter judgment in Plaintiff's favor on Count II of the Complaint, with instructions to vacate the challenged administrative decisions, and enter judgment in Defendant's favor on all remaining claims.

[8] That policy applies to any pending or properly appealed claim for reimbursement of a CGM device or supplies, regardless of date of service, and thus includes Plaintiff's two reimbursement claims at issue in this case.

DATED this 3rd day of October, 2022.

Vanessa R. Waldref
United States Attorney

s/John T. Drake
Brian M. Donovan
John T. Drake
Assistant United States Attorneys

CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2022, I caused to be delivered via the method listed below the document to which this Certificate of Service is attached (plus any exhibits and/or attachments) to the following:

NAME & ADDRESS	**Method of Delivery**
Roger Townsend BRESKIN JOHNSON TOWNSEND 1000 Second Ave., Suite 3670 Seattle, WA 98104	☒CM/ECF System ☐Electronic Mail ☐U.S. Mail ☐Other: _____
James Pistorino PARRISH LAW OFFICES 788 Washington Road Pittsburgh, PA 15228	☒CM/ECF System ☐Electronic Mail ☐U.S. Mail ☐Other: _____

s/John T. Drake
John T. Drake